

CLAIMS

4. ~~A method associated with analytical methods in a flow matrix, which methods utilize biospecific affinity reactions to detect an analyte in a sample, and which comprises:~~
- i. allowing the sample (analyte) and an analytically detectable reactant (Reactant*) migrate through flow channels in a flow matrix to a detection zone (DZ) located in the matrix, in which there is a firmly anchored biospecific affinity reactant (Capturer), wherein
 - ii. Reactant* is captured in the detection zone (DZ) in an amount, being related to the amount of analyte in the sample, **characterized** in that
 - A) Reactant* has particles as an analytically detectable group, and
 - B) the Capturer is anchored to the matrix via immobilized particles, which preferably exhibit ~~hydrophilic groups on their surface.~~
2. The method according to claim 1, ~~characterized~~ ^{wherein} in that the flow occurs laterally in the matrix.
3. The method according to claim 1 ~~or 2, characterized~~ ^{wherein} in ~~that~~ the flow is driven by capillary forces.
4. ~~The method according to any of the claims 1-3, characterized in that the Capturer is capable of binding via biospecific affinity a reactant which in turn binds analyte biospecifically.~~
5. The method according to claim 4, ~~characterized~~ ^{wherein} in that said reactant is applied with the sample or is predeposited in the matrix upstream of the detection

zone (DZ) such that the reactant can react with analyte before reaching the detection zone (DZ).

6. The method according to any of claims 1-5,
characterized in that the particles anchoring the
Capturer have a size which is smaller than the smallest
inner dimension of the flow channels of the matrix.
7. The method according to any of the claims 1-6,
characterized in that the particles, which anchor the
Capturer, have a size being in the range of 0.1-1000
 μm , preferably the range of 0.1-100 μm .
8. The method according to any of the claims 1-7,
characterized in that the label particles have a
diameter in the range of 0.01-5 μm .
9. The method according to any of the claims 1-8,
characterized in that the flow channels have the
smallest inner dimension in the range of 0.4-1000 μm ,
preferably 0.4-100 μm .
10. The method according to any of the claims 1-9,
characterized in that the label particles are
fluorescent or coloured.
11. The method according to any of the claims 1-10,
characterized in that Reactant* is predeposited in the
matrix upstream of the detection zone (DZ) and
preferably upstream of the sample application site.
12. The method according to any of the claims 1-11,
characterized in that the particles, which anchor the
Capturer to the matrix, are a synthetic polymer or a
semisynthetic polymer or a biopolymer which on its
surface exhibits hydrophilic groups.

~~13. The method according to any of the claims 1-12,~~

~~characterized in that the determination method is of sandwich type in which Reactant* is captured in the detection zone (DZ) by formation of the ternary complex Reactant'---analyte---Reactant*, wherein Reactant' and Reactant* are able to simultaneously bind analyte biospecifically and Reactant' is the firmly anchored Capturer or a reactant to which the Capturer may bind via biospecific affinity.~~

~~14. The method according to claim 13, characterized in that the analyte is an antibody with specificity for either Reactant' or Reactant*, and that~~

~~a) Reactant' is an antigen/hapten and Reactant* is an antibody directed to a constant antibody region on the analyte, when the antibody specificity of the analyte is directed to Reactant', or~~

~~b) Reactant* is an antigen/hapten and Reactant' is an antibody directed to a constant antibody region on the analyte, when the antibody specificity of the analyte is directed to Reactant'.~~

~~15. The method according to claim 13, ^{wherein} characterized in that the analyte is an antigen and Reactant' and Reactant* are antibodies with specificity for epitopes on the analyte.~~

~~16. The method according to any of the claims 13-14, characterized in that the analyte is of IgE class directed to an allergen.~~

~~17. The method according to any one of the claims 1-16, characterized in that the determination method is~~

~~performed in connection with diagnosing allergy or autoimmune disease.~~

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18. A test kit for performing analytical methods in a flow matrix, which methods utilize biospecific affinity reactions to detect an analyte in a sample, which kit comprises (i) a flow matrix having a detection zone (DZ), in which there is a firmly anchored biospecific affinity reactant (Capturer), and (ii) an analytically detectable reactant (Reactant*), characterized in that

A) Reactant* has particles as an analytically detectable group, and

B) the Capturer is anchored to the matrix via immobilized particles, which preferably exhibit ~~hydrophilic groups on their surface.~~

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19. The kit according to claim 18, ~~characterized in that~~ *wherein* the matrix is a lateral flow matrix.

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20. The kit according to claim 18 or 19, ~~characterized in that~~ *wherein* the flow in the matrix is driven by capillary forces.

~~21. The kit according to any of the claims 18-20, characterized in that the Capturer is capable of binding via biospecific affinity a reactant which in turn binds analyte biospecifically.~~

wherein
22. The kit according to claim 21, ~~characterized in that~~ said reactant is applied with the sample or is predeposited in the matrix upstream of the detection zone (DZ) such that the reactant can react with analyte before reaching the detection zone (DZ).

~~23. The kit according to any one of claims 18-22, characterized in that the particles anchoring the~~

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~~Capturer have a size which is smaller than the smallest inner dimension of the flow channels of the matrix.~~

24. The kit according to any of the claims 18-23,
5 **characterized** in that the particles, which anchor the Capturer, have a size being in the range of 0.1-1000 μm , preferably the range of 0.1-100 μm .
25. The kit according to any of the claims 18-24,
10 **characterized** in that the label particles have a diameter in the range of 0.01-5 μm .
26. The kit according to any of the claims 18-25,
15 **characterized** in that the flow channels have the smallest inner dimension in the range of 0.4-1000 μm , preferably 0.4-100 μm .
27. The kit according to any of the claims 18-26,
20 **characterized** in that the label particles are fluorescent or coloured.
28. The kit according to any of the claims 18-27,
25 **characterized** in that Reactant* is predeposited in the matrix upstream of the detection zone (DZ) and preferably upstream of the sample application site.
29. The kit according to any of the claims 18-28,
30 **characterized** in that the particles, which anchor the Capturer to the matrix, are a synthetic polymer or a semisynthetic polymer or a biopolymer which on its surface exhibits hydrophilic groups.
30. The kit according to any of the claims 18-29,
35 **characterized** in that the kit is intended for a determination method of sandwich type in which ~~Reactant* is captured in the detection zone (DZ) by~~

~~formation of the ternary complex Reactant'---analyte---
Reactant*, wherein Reactant' and Reactant* are able to
simultaneously bind analyte biospecifically and
Reactant' is the firmly anchored Capturer or a reactant
to which the Capturer may bind via biospecific
affinity.~~

31. The kit according to claim 30, **characterized** in that
the analyte is an antibody with specificity for either
Reactant' or Reactant*, and that

a) Reactant' is an antigen/hapten and Reactant* is an
antibody directed to a constant antibody region on
the analyte, when the antibody specificity of the
analyte is directed to Reactant', or

b) Reactant* is an antigen/hapten and Reactant' is an
antibody directed to a constant antibody region on
the analyte, when the antibody specificity of the
~~analyte is directed to Reactant*.~~

32. The kit according to claim 30, ~~characterized in that~~ *wherein*
the analyte is an antigen and Reactant' and Reactant*
are antibodies with a specificity for epitopes on the
analyte.

33. The kit according to claim 30 ~~or 31, characterized in~~ *wherein*
~~that~~ the analyte is of IgE class directed to an
allergen.

34. ~~The kit according to any of the claims 18-33,~~
characterized in that the determination method is
performed in connection with diagnosing allergy or
~~autoimmune disease.~~

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